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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/695,293	10/25/2000	Jeanne Bernstein	2786-0140P	9369

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Birch Stewart Kolasch & Birch LLP
PO BOX 747
Falls Church, VA 22040-0747

EXAMINER
KETTER, JAMES S

ART UNIT	PAPER NUMBER
1636	

DATE MAILED: 01/28/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

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APPLICATION NO./ CONTROL NO.	FILING DATE	FIRST NAMED INVENTOR / PATENT IN REEXAMINATION	ATTORNEY DOCKET NO.

EXAMINER

ART UNIT	PAPER
	14

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Commissioner of Patents and Trademarks

--See attached--

Office Action Summary	Application No.	Applicant(s)	
	09/695,293	BERNSTEIN ET AL.	
	Examiner	Art Unit	
	James S. Ketter	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 November 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-34* is/are pending in the application.

4a) Of the above claim(s) *1-3,6-11 and 14-34* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *4,5,12 and 13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *6* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Applicant's election with traverse of Group XLII, claims 4, 5, 12 and 13, in Paper No. 13, filed 21 November 2002, is acknowledged. The traversal is on the ground(s) that other inventions connected to the elected amino aid sequence should be examined as well, as allegedely no burden would be placed on the Office. This is not found persuasive because non-coextensive searches would be needed if the other inventions were included.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-3, 6-11 and 14-34 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 13.

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 4, 5, 12 and 13 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a credible asserted utility or a well established utility.

At page 14 of the specification, first full paragraph, Applicants broadly assert a utility for the claimed invention as being useful for the detection or treatment of diseases involving

regulation of extracellular fluid, particularly hypertension. At page 28, at about midpage, it is set forth that the function of the mineralcorticoid receptor would be to increase hypertension, by way of increased binding of mineralcorticoids or glucocorticoids. At page 48, third full paragraph, it is set forth that the protein products of the invention may be employed to increase levels of such products in a therapeutic method. However, the treatment of hypertension within this receptor system would require reduction of said receptor, not an increase. Therefore, the utility set forth, e.g., at page 48, would not be of use therapeutically. As such, the asserted utility is not credible. Furthermore, there is not a well established utility for the claimed amino acid sequence, especially in light of said sequence being a splice variant, differing substantially from the art-known sequence.

Claims 4, 5, 12 and 13 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention. Furthermore, the following factors have been considered:

The amount of direction or guidance presented in the specification, the presence or absence of working examples and the predictability or unpredictability of the art. As set forth above, the specification does not present either a well-established utility or a credible utility. In particular, the specification fails to teach how to reduce hypertension in a patient using the claimed polypeptide, in view of the teachings in the specification, e.g., at page 48, that increasing the polypeptide is the therapeutic scheme envisioned. It would appear that increasing the receptor levels would exacerbate the hypertensive state in the patient. No examples of such

therapy are provided. Furthermore, a genus of polypeptide variations are encompassed by the instant claims. However, no guidance is available in the specification for determining which variations to employ. In the protein art, the alteration of even a single amino acid can drastically alter the function of a polypeptide, usually by diminishing or eliminating activity. The effect of such a change is generally unpredictable, due to the enormous complexity of the interactions between the amino acid residues of which the polypeptide is composed.

The quantity of experimentation, the nature of the invention and the state of the prior art. It is not clear that any amount of experimentation would permit the skilled practitioner to treat hypertension by increasing the level of a claimed polypeptide in the patient, as such a step would appear to work against the desired outcome of the treatment. Furthermore, it is not apparent that the prior art employed a similar therapeutic method using the art-known splice form of the receptor.

Conclusion. Were the skilled practitioner to have attempted to use the polypeptide of the instant claims to treat hypertension, said practitioner first would have turned to the specification for guidance. However, as set forth above, the overall scheme of the therapy does not appear to be workable, and the specification provides no guidance of examples in selecting a manner in which hypertension might be reduced by the polypeptide. Furthermore, no teaching is presented to determine which of the claimed genus of polypeptides would be expected to operate as disclosed. Next, said practitioner would have turned to the prior art for guidance in practicing such a therapeutic method. However, as noted above, the prior art did not practice such a method with the art-known splice form of the polypeptide, and thus would not have provided the required teachings to the practitioner. Finally, the skilled practitioner would have been forced to

rely upon empirical experimentation to devise a method for reducing hypertension using the claimed polypeptide. However, without guidance, in view of the overall scheme appearing to work in the opposite fashion from that needed to treat the condition, and further in view of the unpredictability of the effects of changes in the sequence of a polypeptide, such experimentation would have been undue.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 4, 5, 12 and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Arriza et al. (U, newly cited).

In view of the unclear metes and bounds of the instant claims with respect to inclusion or exclusion of the art-known form of the polypeptide (see the rejection under 35 USC § 112, second paragraph, below), the instant claims may be construed as encompassing the art-known form. Arriza et al. teaches the cDNA encoding this form of hMR, and at the legend of Figure 4 teaches that this polypeptide was expressed. Also, at page 271, at the second full paragraph in the left-hand column, and the paragraph bridging the columns, it is taught that hMR was recombinantly expressed, and that the extracts containing the polypeptide were then employed in biochemical assays. The physiological conditions used in such assays would inherently made

use of buffers or diluents which would not hinder function of the polypeptide. Such buffers or diluents would have been inherently acceptable as diluents in a pharmaceutical for this reason.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4, 5, 12 and 13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With respect to instant claims 4, 5, 12 and 13, the phrase "where the amino acid sequence differs from the original amino acid sequence, coded by the original nucleic acid sequence from which the variant has been varied" is unclear, as it is not clear from the specification what the "original" sequence is for the claimed polypeptide. As noted above in the rejection under 35 USC § 102(b), the instant claims thus do not clearly exclude the art-known, and presumably prevalent, splice form of the polypeptide.

With further respect to instant claims 4, 5, 12 and 13, each of the instant claims depends from a non-elected claim. The language of the non-elected claims as needed to complete each of the instant claims should be imported, such that the instant claims will be complete when the non-elected claims are cancelled, should the instant claims pass to issue.

With still further respect to instant claims 4, 5, 12 and 13, each of the instant claims is drawn to non-elected subject matter in addition to the elected invention. It is noted that Applicants have traversed the restriction requirement. However, Applicants have not actually

provided arguments against the restriction between the amino acid sequences of SEQ ID NOS:27-52. In view of this, it would appear that Applicants would have to cancel such non-elected subject matter should the instant claims pass to issue.

Certain papers related to this application may be submitted to the directly to the Examiner by facsimile transmission at (703) 746-5155. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993)(see 37 CFR ' 1.6(d)). To send the facsimile to the Art Unit instead, the Art Unit 1636 Fax number is (703) 305-7939. NOTE: If Applicant does submit a paper by fax to this number, the Examiner must be notified promptly, to ensure matching of the faxed paper to the application file, and the original signed copy should be retained by Applicant or Applicant's representative. (703) 308-4242 or (703) 305-3014 may be used without notification of the Examiner, with such faxed papers being handled in the manner of mailed responses. Applicant is encouraged to use the latter two fax numbers unless immediate action by the Examiner is required, e.g., during discussions of claim language for allowable subject matter. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the Examiner with respect to the examination on the merits should be directed to James Ketter whose telephone number is (703) 308-1169. The Examiner normally can be reached on M-F (9:00-6:30), with alternate Fridays off.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Remy Yucel, can be reached at (703) 305-1998.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

Jsk
January 24, 2003

JAMES KETTER
PRIMARY EXAMINER